K040020

FEB 18 2004

510(k) SUMMARY

Submitter's Name: C.T.M. Homecare Product, Inc.
1663 Iowa Ave.
Riverside, CA 92507
(909) 788-8168

Date summary prepared: December 23, 2003

Device name:

Proprietary name:	C.T.M. Power Chair HS-1000
Common or usual name:	Power chair.
Classification name:	Powered wheelchair, Class II, 21 CFR 890.3860.

Legally marketed device for substantial equivalence comparison:

C.T.M. Power Chair HS-5600 submitted by Warepalmy Enterprise LLC (USA) and cleared for marketing under 510(k) #K002983.

Description of the device:

The C.T.M. Power Chair HS-1000 is an indoor/outdoor powered wheelchair that is battery operated. It has a base with four wheels, an adjustable padded seat with armrests, and a controller attached to one armrest which allows the rider to control the movement of the chair. It can be disassembled for transport and is provided with an on-board battery charger.

Intended use of device:

The device is an indoor/outdoor powered wheelchair that provides transportation for a disabled or elderly person.

Technological characteristics:

The device features and use parameters of the C.T.M. Power Chair HS-1000 and the C.T.M. Power Chair HS-5600 are very similar. Both are battery operated, have two motors, and have automatic braking systems. Batteries and charging recommendations are identical. Built-in battery chargers are provided with both wheelchairs. Use parameters are very similar, varying only in minor parameters such as turning radius.

Testing conducted:

Tests listed in the *Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three Wheeled Vehicles*, July 1995, were conducted and the results included in the subject 510(k) submission.

Performance testing:

Comparative performance testing and clinical evaluations were not submitted as part of this 510(k).

SECTION 3 - INTENDED USE

Intended use of device:

The C.T.M. Power Chair HS-1000 is an indoor/outdoor powered wheelchair that provides transportation for a disabled or elderly person.

Intended use of predicate device:

The C.T.M. Power Chair HS-5600 is an indoor/outdoor powered wheelchair that provides transportation for a disabled or elderly person.

Comparison:

The intended uses of the two products are identical. Each provides increased mobility for one individual, who is also the operator. Each device can be used in indoor and outdoor settings.

Labeling:

The intended use of the C.T.M. Power Chair HS-1000 is in the Owner's Manual found in Appendix II on the first page after the cover. The intended use of the HS-5600 is in the Owner's Manual found in Appendix V on the first page after the cover.

SECTION 4 - DEVICE INFORMATION

Executive Summary

The C.T.M. Power Chair HS-1000 is an indoor/outdoor powered wheelchair that is battery operated. It has a base with four wheels, an adjustable padded seat with armrests, and a controller attached to one armrest which allows the rider to control the movement of the chair. It can be disassembled for transport and is provided with an on-board battery charger.

The C.T.M. Power Chair HS-1000 is a new device, not a modification of a previously cleared device. Numerous powered wheelchairs are currently on the market.

Device Description

Wheelchair

The C.T.M. Power Chair HS-1000 is a battery-powered wheelchair with four wheels. The design of this wheelchair is quite similar to other power chairs that are already on the market. The wheelchair has a sturdy base, which contains the motors, provides spaces for the two batteries, and supports the padded seat. The seat has adjustable armrests and footrest. There is a controller with a joystick that attaches to either armrest and allows the rider to control the movement of the power chair. The rear wheels are 10" in diameter and the front wheels are 7". The diagrams in Appendix I show the wheelchair's features and dimensions. Diagram 1 shows photographs of the wheelchair with the major parts labeled. Diagram 2 shows front, rear, and side views of the C.T.M. Power Chair HS-1000 with major dimensions given.

If desired, the wheelchair can be disassembled to provide easier transport. There are 5 components: the base, the cover, the seat with attached controller, and two batteries. The base section weighs 86 lbs. The assembled chair without batteries weighs 120 lbs. With batteries, the chair weighs approximately 175 lbs. Assembly of the chair is simple and does not require any tools.

In the assembled wheelchair, the motors and batteries are located in the base unit. The controller/joystick unit is attached to the batteries with a cable that runs from the controller to the rear of the base. There are two motors in the base. They have a maximum 420w. There is a circuit breaker in the electrical line that will trip if electrical circuits are overloaded. Circuit breaker activation usually denotes a temporary event. The rider can push the circuit breaker and normal operation will usually be restored.

The braking system is automatic and electric. It is on the rear drive wheels only. The brakes are automatically "on" except when the wheelchair is turned on and the joystick has been moved away from the neutral position. When the joystick is released or moved back to neutral the brakes engage again. If the electrical brake system fails, the brakes will default to the closed or "brakes on" position, thereby

stopping the wheelchair. Braking time is 1.0 seconds and braking distance is about 10 feet. Diagram 3 in Appendix I shows the operating system which includes the brakes.

The C.T.M. Power Chair HS-1000 has a free-wheeling device located on the left-hand side of the base by the seat cushion. The normal position of the lever is "D". In this position the power wheelchair will not move without turning on the key and having charged batteries. Moving the lever to the position marked "N" allows the wheelchair to be rolled freely without the key being turned on. This feature is very useful when maneuvering the wheelchair for battery charging or storage. The power chair is not intended to be ridden at all in this free-wheeling mode.

The power chair is controlled by the rider using the hand controls on the controller unit. It can be attached to either armrest. The controller unit is a Shark Model Controller from Dynamic Controls, Ltd. It is a relatively new controller that is being used on a variety of power chairs. It consists of a controller box, joystick, electrical cable, and imbedded software. Diagram 4 in Appendix I shows pictures of the controller unit with the parts labeled. The joystick is used to move the wheelchair. When it is in the central, neutral position, the wheelchair is stopped. If the joystick is pushed forward, the wheelchair moves forward. Pushing the joystick farther forward increases the speed at which the wheelchair moves. Pulling the joystick backward causes the wheelchair to move backwards, speed again proportional to the movement of the joystick. To turn the wheelchair, the joystick is moved in the direction of the desired turn. The minimum turning radius is 30.7". When the joystick is released, it automatically returns to the neutral position and the wheelchair comes to a stop.

The controller has an on-off switch, speed dial, power reserve indicator, and horn button. The on-off switch regulates the power to the unit. The wheelchair will not move unless the power is on and the batteries are charged. The speed dial adjusts the maximum speed that the wheelchair will go in either forward or reverse directions. The maximum forward speed is 4.5 mph. The maximum reverse speed is 2.1 mph. Turning the speed dial counterclockwise reduces the maximum speed, turning it clockwise increases the maximum speed. The horn button sounds the horn. The power reserve indicator shows the battery reserve. It consists of a series of red lights. When these lights are steady and completely lit, the batteries are fully charged. When only a few lights are lit, the batteries should be recharged as soon as possible.

The power reserve indicator also acts as a self-diagnostic warning light when it flashes to indicate selected problems with the power chair. Generally speaking, the wheelchair can not be driven when this light is flashing. The number of flashes helps determine the problem. The self-diagnostic signals are:

Number of flashes	Problem
0 – no lights	battery is not connected correctly
1	user fault – release joystick and try again
2	battery fault
3	left motor fault
4	right motor fault
5	left park brake fault
6	right park brake fault
7	controller unit fault
8	power module fault
9	communications fault
10	unknown fault
11	incompatible controller unit

Detailed explanations of these problems and solutions to them are given in the Troubleshooting section of the Owner's Manual for the power chair, which can be found in Appendix II.

The battery charger is on-board. It is a 3A charger. It plugs into a standard 110 volt wall socket or into a 220 volt socket.

Batteries

The C.T.M. Power Chair HS-1000 runs on two 12 volt SLA (sealed lead acid) batteries. These batteries are provided with the wheelchair. Replacements can be obtained from the distributor or other local sources.

Accessories

There are no optional accessories at this time.

Regulatory Status

The C.T.M. Power Chair HS-1000 is a new device that has not been previously submitted to the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2004

C.T.M. Homecare Product, Inc.
C/o Mr. Robert S. McQuate
R.S. McQuate & Associates, Inc.
1630 Dutch Ravine Court
Reno, Nevada 89521

Re: K040020
Trade/Device Name: C.T.M. Power Chair HS-1000
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: December 29, 2003
Received: January 6, 2004

Dear Mr. McQuate:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): _____

Device name: C.T.M. Power Chair HS-1000

Indications for Use:

The C.T.M. Power Chair HS-1000 is an indoor/outdoor powered wheelchair that provides transportation for a disabled or elderly person.

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040020